The Pending Claims

Claims 1, 3, 4 and 13-23 are currently pending. All claims are directed to the method of treating cancer.

Amendments to the Claims

Claims 1 and 13 were amended and claims 16-23 were added to point out more particularly and distinctly the subject matter of the present invention. No new matter was added by way of these amendments as the amendments are supported by, for example, claim 9 and Table 4.

The Office Action

Claims 1, 3, 4 and 13-15 were rejected under 35 U.S.C. § 103 as obvious in view of and, therefore, unpatentable over (i) Rao et al. or Tso et al. as defined in footnotes 18 and 20 of Wu et al. or (ii) Qian or Kim et al. as set forth in lines 11-15 of page 1 of the instant application. Reconsideration of this rejection is hereby requested.

Discussion of Rejection under 35 U.S.C. § 103

Claims 1, 3, 4 and 13-15 were rejected under Section 103 as obvious in view of and, therefore, unpatentable over Rao et al., Tso et al., Qian, or Kim et al. According to the Office, the cited references disclose that gossypol is an agent that is effective against cancer, including breast cancer, in mammals. Based on these references, the Office concludes that the

instantly claimed method of treating cancer is obvious. This rejection is traversed for reasons set forth below.

Rao et al. is directed to the inhibition of tumors in three murine tumor models. Although an increase in the life span of about 60% of mice afflicted with adenocarcinoma was observed at an optimal dose of 0.5 mg/mouse, no increase in the life span of mice afflicted with P388 or L1210 leukemia was observed. In addition, survival rate decreased sharply at doses below and above the optimal dose. At the suboptimal doses, the mice died from the effects of the tumors. At the supraoptimal doses, the mice died from toxic effects of the drug.

Accordingly, one of ordinary skill in the art, upon reading Rao et al., would not be motivated to attempt to use gossypol, gossypolone, pharmaceutically acceptable salts thereof, or combinations thereof in the treatment of cancer in humans because Rao et al. teaches that doses below on the order of 10 mg/kg/d in mice are ineffective in inhibiting tumors and that doses above on the order of 10 mg/kg/d in mice are toxic. Therefore, Rao et al. actually teaches away from the present invention. Furthermore, as pointed out in the instant specification at, for example, page 4, line 25, through page 5, line 4, applicants have surprisingly and unexpectedly discovered that gossypol and related compounds at doses approximately one-tenth of the optimal dose taught by Rao et al. are effective in inhibiting tumors in humans without causing toxicity. In addition, Rao et al. neither teaches nor suggests the blood levels, dosages and routes of administration

of gossypol, gossypolone, and pharmaceutically acceptable salts thereof, alone or in various combinations, as taught (for example, in Table 4), and claimed in the instant application.

Tso is directed to the inhibition of Ehrlich ascites tumor cell proliferation. Erlich ascites tumors do not even occur in humans. Accordingly, Tso can hardly be said to teach or suggest the use of gossypol, gossypolone, and pharmaceutically acceptable salts thereof, alone or in various combinations, in the treatment of human cancers. Furthermore, as noted above, with respect to Rao et al., Tso neither teaches nor suggests the blood levels, dosages and routes of administration of gossypol, gossypolone, and pharmaceutically acceptable salts thereof, alone or in various combinations, as taught (for example, in Table 4) and claimed in the instant application.

Qian and Kim et al. are directed to the spermicidal effects of gossypol. Accordingly, neither reference teaches or suggests the use of gossypol, gossypolone, and pharmaceutically acceptable salts thereof, alone or in various combinations, in the treatment of cancer in humans as taught and claimed in the instant application.

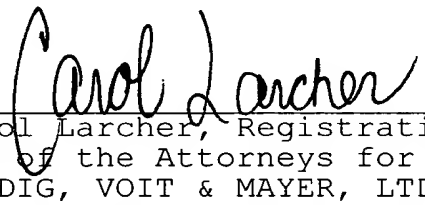
In view of the above, Applicants submit that the present invention as claimed is neither taught nor suggested by the cited references, taken alone or in various combinations. Therefore, the present invention is unobvious in view of and, therefore, patentable over the cited references. Accordingly, Applicants request withdrawal of this rejection.

Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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